IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

PAMELA BUTLER,	)	
	)	
Plaintiffs,	)	Case No. 4:18-cv-01701-AGF
v.	)	
	)	Lead Case
MALLINCKRODT LLC, et al.	)	
	)	**ORAL ARGUMENT REQUESTED**
Defendants.	)	

DEFENDANT MALLINCKRODT LLC'S MEMORANDUM IN SUPPORT OF ITS MOTION TO EXCLUDE THE TESTIMONY OF PLAINTIFFS' EXPERT JAMES WELLS, PH.D

Defendant Mallinckrodt LLC ("Mallinckrodt") respectfully moves the Court for an Order excluding the testimony of plaintiffs' expert James Wells, Ph.D. because he is not qualified to offer opinions regarding compliance with federal radiation safety standards and his opinions and bases do not satisfy the requirements of either Federal Rule of Evidence 702 or *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

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I. INTRODUCTION

Plaintiffs' sole cause of action alleges Mallinckrodt breached its duties under the Price-Anderson Act ("PAA"), 42 U.S.C. § 2011 *et seq*. (Doc. #1).[1] In an effort to prove Mallinckrodt breached its standard of care under the PAA, Plaintiffs offer the testimony of James Wells, Ph.D. Federal Rule of Evidence 702 and the United States Supreme Court's *Daubert* line of cases require the Court to determine whether the proffered testimony is scientifically reliable and probative before presented to a lay jury. The testimony of Dr. Wells should be struck in its *entirety* and is not reliable or probative for the following reasons:

- Dr. Well's opinion that Mallinckrodt released radon-222 in excess of the limit in 10 C.F.R. § 20.106 is based on an improper methodology and factual assumptions directly contradicted by the record.
- Dr. Wells' opinion that Mallinckrodt released thorium-230 in excess of the limit in 10 C.F.R. § 20.106 is based on an improper methodology contradicted by the very regulations he purports to use.
- Dr. Wells' supplemental opinion regarding releases of radionuclides in sediment is pure *ipse dixit* unsupported by any relevant data.
- Dr. Wells' allocation opinions regarding the alleged releases attributable to Mallinckrodt are not based on a reliable methodology or sufficient facts or data.
- Dr. Wells is simply not qualified to render opinions on compliance with federal radiation safety standards, including 10 C.F.R. § 20.106.

II. BACKGROUND

Plaintiffs each allege that their four distinct illnesses were caused by exposure to radioactive material released in excess of federal regulations by Mallinckrodt and Cotter Corporation ("Cotter"). (Doc. #1, ¶ 24.) With respect to Mallinckrodt, Plaintiffs' claims—and Dr. Wells' opinions—focus on its operation of the St. Louis Airport Site ("SLAPS"), a 21-acre

[1] Plaintiffs' four Complaints were filed as Doc. #1 in their individual cases: Pamela Butler, 4:18-cv-01701; Kenneth Koterba, 4:18-cv-01702; Anthony Hines, 4:18-cv-01703; and Emery Wallick, 4:18-cv-01704. The Complaints are identical except for the biographical information in paragraph 24. Mallinckrodt will refer to the Complaints as Doc. #1.

site north of the St. Louis Airport. (Doc. #1, ¶ 29; Wells Report, generally, attached as **Exhibit A**.) The Manhattan Engineer District ("MED")—the code name for the U.S. Army's Manhattan Project—acquired SLAPS in 1946. (Doc. #1, ¶ 29.) The MED, and its successor the Atomic Energy Commission ("AEC"), operated and stored radioactive waste product at SLAPS from approximately 1946 until July 1953. (SLAPS Historical Synopsis, p. 1, attached as **Exhibit B**.) The AEC contracted with Mallinckrodt to operate the government-owned facility from July 1953 to February 14, 1966. (Wells Report, p. 12; Wells Exhibit 6, attached as **Exhibit C**.)

Against this historical backdrop, Plaintiffs retained Dr. Wells to review environmental data for SLAPS and Latty Avenue—a separate site downstream, operated by Cotter—to "see if he could determine concentrations in air and water of radionuclides, and compare them to the effluent limitations in the federal code, 10 C.F.R. Section 20." (Wells Depo., 54:1–11, attached as **Exhibit D**.) Dr. Wells' scope of work subsequently expanded to include evaluating the "standard of care" and contaminant fate and transport[2] of sediments in Coldwater Creek. (Wells Depo., 54:12–20.) Dr. Wells opined that Mallinckrodt released radioactive material from SLAPS in excess of 10 C.F.R. § 20.106 (1960) in three ways: (1) radon releases from 1948 to 1966; (2) thorium-230 in 1960, and (3) unspecified radionuclides for an unspecified time period in soil and sediment. (Wells Report, pp. 14, 16; Wells Supplemental Report, p. 7–9, attached as **Exhibit E**.) Additionally, he purports to allocate releases between Mallinckrodt and Cotter. (Wells Report, p. 19–22.)

Significant errors in Dr. Wells' methodology and a complete lack of factual foundation render his opinions scientifically unreliable. However, on a more fundamental level, the record in this matter exposes Dr. Wells' erroneous analysis. Mallinckrodt was a contractor to the U.S. Government, and the MED—and later AEC—provided oversight and supervision of

[2] Fate and transport analyses model a chemical's travel within an environment.

Mallinckrodt's activities. (Fleishman-Hillard, p. 123; 145–46, attached as **Exhibit F**.) Pursuant to its contract, Mallinckrodt submitted environmental testing to the government, and these reports have been produced in discovery. If Mallinckrodt violated federal radiation safety standards during its operation of SLAPS, these government agencies would have documented these violations and taken action against Mallinckrodt. Yet Dr. Wells concedes after reviewing all of the records, including AEC inspection reports, that he has not seen a single notice of non-compliance issued to Mallinckrodt. (Wells Depo., 149:10–150:5.)

III. STANDARD OF REVIEW

Federal Rule of Evidence 702 governs the admissibility of expert testimony. Under Rule 702, a witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

(a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue:

(b) the testimony is based upon sufficient facts or data;

(c) the testimony is the product of reliable principles and methods; and

(d) the witness has applied the principles and methods reliably to the facts of the case.

Rule 702 imposes a "gate-keeping function" on district courts to ensure that "any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589 (1993). "The objective of the *Daubert* inquiry 'is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.'" *Am. Auto. Ins. Co. v. Omega Flex, Inc.*, 783 F.3d 720, 722 (8th Cir. 2015) (quoting *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999)). Moreover, the party offering the expert testimony bears the burden of establishing its admissibility. *Marmo v.*

Tyson Fresh Meats, Inc., 457 F.3d 748, 757-58 (8th Cir. 2006) (citing *Daubert* , 509 U.S. at 589–90).

Daubert enumerates several non-exclusive factors to guide this Court's reliability analysis:

- whether the expert's technique or theory can be or has been tested—that is, whether the expert's theory can be challenged in some objective sense, or whether it is instead simply a subjective, conclusory approach that cannot reasonably be assessed for reliability,
- whether the technique or theory has been subjected to peer review or publication,
- the known or potential rate of error of the technique or theory when applied,
- the existence and maintenance of standards and controls, and
- whether the technique or theory has been generally accepted in the scientific community.

Daubert, 509 U.S. at 593–94; Fed. R. Evid. 702, advisory committee's notes. "*Daubert's* progeny provides additional factors such as: whether the expertise was developed for litigation or naturally flowed from the expert's research; whether the proposed expert ruled out other alternative explanations; and whether the proposed expert sufficiently connected the proposed testimony with the facts of the case." *Lauzon v. Senco Products, Inc.*, 270 F.3d 681, 687 (8th Cir. 2001).

Further, "[w]hen the analytical gap between the data and proffered opinion is too great, the opinion must be excluded." *Marmo*, 457 F.3d at 758. And when an opinion rests on faulty or insufficient data, or otherwise ignores relevant data, it is proper for a district court to exclude such testimony. *Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1057 (8th Cir. 2000).

IV. ARGUMENTS & AUTHORITIES

A. Dr. Wells' Opinions That Mallinckrodt Violated 10 C.F.R. § 20.106 Are Based on an Improper Methodology Contradicted by the Record and the Regulations.

In his two reports, Dr. Wells alleges Mallinckrodt released radioactive material in excess of the limits imposed by 10 C.F.R. § 20.106 (1960) in three respects. As explained below, none of these opinions are admissible under Federal Rule of Evidence 702 or *Daubert*.

1. Dr. Wells' Radon-222 Opinion Does Not Follow the Established Methodology for Determining Compliance with the Applicable Regulatory Radiation Release Limits.

Dr. Wells claims radon-222 was released from SLAPS in amounts exceeding the regulatory limit for the years 1948 to 1966. (Wells Report, p. 14.) Dr. Wells' *sole* basis for this opinion is a 1948 radon-release measurement that he compares to the 1960 regulatory limit. (Wells Report, p. 14; Wells Depo., 171:23–172:1; Depo. Ex. 8, attached as **Exhibit G**.) As detailed below, Dr. Wells' radon-emission opinion uses an improper methodology and is based solely on a measurement related to material removed long before Mallinckrodt operated SLAPS.

The March 1948 document Dr. Wells cites for the radon measurement identifies "the source of this contamination [as] the K-65." (Wells Report, p. 14; Depo. Ex. 8.) K-65 was a radium-bearing residue that produced radon. (Wells Depo., 176:2–8.) Because the K-65 produced excessive radon—as shown in the document Dr. Wells cited—the material was removed from SLAPS by the end of 1949, *four years before Mallinckrodt started operating SLAPS.* (SLAPS Historical Synopsis, p. 2; Wells Depo. Ex. 9, attached as **Exhibit H**.) Thus, the measurement Dr. Wells relies on for his radon opinion was moot by the end of 1949 and irrelevant to Mallinckrodt's activity from 1953 to 1966. Dr. Wells' report cryptically admits "material was progressively removed from the site starting in the 1950s," but he failed to explain the removed material was the source of his only measurement. (Wells Report, p. 14.) At his

deposition, however, Dr. Wells admitted knowing the K-65 material was removed from SLAPS. (Wells Depo., 176:9–13.) Rather than admit the removal of the K-65 renders his opinion baseless, Dr. Wells doubled down on the irrelevant data and absurdly argued this 1948 measurement can be used for determining compliance with the relevant regulatory limit for the next *18 years*. (Wells Depo., 183:23–184:11.)

Dr. Wells also clearly failed to employ a reliable methodology for assessing compliance with the relevant regulatory limit, 10 C.F.R. § 20.106 (1960). Section 20.106, Appendix B, *Concentrations in Water and Air above Natural Background*, Table II, limits releases of radioactive material from a facility. (Federal Register, Exhibit 11, p. 8596, 8600, attached as **Exhibit I**.) In determining compliance with the limits of § 20.106, measured "concentration[s] [of radioactive material] may be averaged over the course of a year." § 20.106(b). Annual averages are used because the limits are based on the annual dose limit to exposed persons. (Federal Register, Exhibit 11, p. 8596.) "Under § 20.106, [p]laintiffs [are] required to show a breach using annual averaging." *McMunn v. Babcock & Wilcox Power Gen. Grp.*, 869 F.3d 246, 267 (3d Cir. 2017). "[D]ata relating to individual moments in time fail[] to show a breach." *Id.* Stated differently, tort plaintiffs in a PAA case cannot claim a violation of the standard based on one *discrete* measurement. *Id.* at 266.

Dr. Wells' methodology runs afoul of this annual average requirement provided in § 20.106(b) and *McMunn* because it requires annual average data for each year being evaluated. Dr. Wells relies solely on a single measurement from 1948 for his opinion that excessive radon-222 was released from SLAPS. (Wells Report, p. 14; Wells Depo., 171:23–172:1.) He provides no data for any year after 1948. Indeed, Dr. Wells even admitted not having sufficient information to reconstruct or determine the annual average release rates. (Wells Depo., 183:23–

184:11.) As such, Dr. Wells lacks any evidence to show a breach of § 20.106 with respect to radon-222 for any year. He has merely pointed to a single (wholly irrelevant) measurement and claimed breach for an 18-year period. *McMunn* and § 20.106, as well as Rule 702, reject this methodology.

These undisputed facts demonstrate that Dr. Wells' radon-emission opinion fails to follow the methodology of § 20.106 and is unreliable. The analytical gap between the data (a single 1948 measurement) and his proffered opinion (spanning nearly two decades, when conditions indisputably changed) is simply too great. Therefore, Dr. Wells' opinion regarding radon-222 releases from SLAPS will not assist the jury and must be excluded.

2. Dr. Wells' Thorium-230 Opinion Does Not Follow the Established Methodology for Determining Compliance with the Applicable Regulatory Radiation Release Limits.

Dr. Wells also contends Mallinckrodt released thorium-230 in excess of the regulatory limit from SLAPS in 1960. (Wells Report, p. 16–17, Table 2.) There are two problems with his analysis. First, as established above, using a single measurement, rather than the annual average, to determine non-compliance is improper under the regulation and caselaw. Second, Dr. Wells compared the single estimated measurement to the limit for a different type of thorium-230 than that present at SLAPS. As outlined below, when the annual average is used and the thorium is properly characterized, the data shows Mallinckrodt did not release excessive thorium-230 in 1960.

a. Dr. Wells failed to use annual average releases as required by 10 C.F.R. § 20.106.

Dr. Wells relies on Mallinckrodt's 1960 annual monitoring report to support his thorium-230 opinion. (Wells Report, p. 16; Wells Ex. 10.) The report details 12 different radiation measurements at SLAPS (Wells' mistakenly claims four measurements). (Wells Report, p. 16;

Wells Ex. 10, attached as **Exhibit J**.) Despite the prescription of 10 C.F.R. § 20.106 to use annual averaged data, Dr. Wells uses the *highest* measurement from these tests instead of the annual average listed in the report. (Wells Report p. 16.) Next, Dr. Wells used a table created by Mallinckrodt's experts Risk Assessment Corporation showing the activity fractions of radionuclides in the air to estimate the approximate amount each radionuclide contributed to the total 1960 measurement. (Wells Report, p. 16; Table 2.) This provides Dr. Wells with an estimate of the thorium-230 in the *highest* release measured. Dr. Wells contends that single estimate of thorium-230 violated the regulatory standard.

The release limits for thorium-230, as with radon, are stated in § 20.106, Appendix B, *Concentrations in Water and Air above Natural Background*, Table II. (Federal Register, Exhibit 11, p. 8596, 8600.) Compliance is again determined by comparing measured concentrations "averaged over the course of a year" to the limits stated in Appendix B to § 20.106(b). *McMunn*, 869 F.3d at 267. Discrete measurements of maximum concentrations at a single point in time are not evidence of a breach. *Id*.

Contravening the language of § 20.106, *McMunn*, and established radiation safety practices, Dr. Wells also used the single *highest* measurement, not the annual average, to evaluate compliance. (Wells Depo., 188:15–189:6; 193:15–19.) He acknowledged the 1960 testing data contained an annual average. (Wells Depo., 195:23–196:7.) The average was approximately 60 percent less than the maximum number Wells used for his calculations. (Wells Ex. 10.) Demonstrating his lack of expertise, Wells insisted he did not need to use the annual average measurement. (Wells Depo., 189:7–20; 197:22.) When showed the standard calling for annual averaging, Dr. Wells latched on to the phrase "may be used" to justify his use of the single, maximal measurement and claimed, as a paid litigation expert, he gets to determine

whether to average measurements or use the highest measurement. (Wells Depo., 197:22–198:12; 199:10–17.) In essence, Dr. Wells argues, sixty years after the fact, he has discretion to bias the results in his client's favor by ignoring averaged data.

But the *McMunn* court expressly rejected these same arguments. Plaintiffs in *McMunn* argued they could "decline annual averaging, allowing them to find breaches of duty where emissions exceeded the maximum permissible concentrations over short periods of time." 869 F.3d at 260. Like Dr. Wells, the *McMunn* plaintiffs based their argument solely on the word "may" in § 20.106. *Id.* at 266. Rejecting plaintiffs' argument, the court explained the AEC, not tort plaintiffs, had discretion whether to use annual averaging. *Id.* Under § 20.106, tort plaintiffs are "required to show a breach using annual averaging." *Id.* at 267. Dr. Wells admitted he did not use annual averaging data to support his opinion that Mallinckrodt violated § 20.106 in 1960 by releasing thorium-230. Consequently, his opinion is based on an incorrect interpretation of the regulation, an unreliable methodology, and fails to fit the factual information. As such, his opinion would not help the jury determine a material issue.

b. Dr. Wells used the wrong release limit for *insoluble* thorium-230.

Dr. Wells also mistakenly chose to use the release limit for soluble thorium, which is significantly lower than the limit for the *insoluble* thorium present at SLAPS, for analyzing releases of thorium-230 from SLAPS in 1960. Appendix B, Table II, to § 20.106 provides release limits for soluble and insoluble forms of most isotopes, including thorium-230. (Federal Register, Exhibit 11, p. 8603.) Proper characterization of the radionuclide is critical because release limits differ based on solubility—ability to dissolve in water. (Federal Register, Exhibit 11, p. 8603.) In the case of thorium-230, the release limit for soluble material (8 x 10^{-14} uc/cc) is nearly an order of magnitude less than the release rate for insoluble material (3 x 10^{-13} uc/cc).

(Wells Depo., 202:13–22.) Dr. Wells understood his decision to use the soluble limit for thorium-230, instead of insoluble, significantly reduced the release limit. (Wells Depo., 202:13–22.) Yet, if the correct insoluble limit is used, there can be no dispute that all results were compliant. (Wells Depo., 213:5–18.)

Dr. Wells has not offered an opinion that justifies his misclassification of the form of the isotope. Thorium-230 is an isotope of the element thorium that exists in various chemical forms. (Agency for Toxic Substances and Disease Registry ("ATSDR"), *Toxicological Profile for Thorium*, pp. 69–72, attached as **Exhibit K**.) Discovery materials and scientific literature address the solubility of the thorium-230 at SLAPS. Specifically, in 1986, Dick Duffey, Ph.D., of the University of Maryland analyzed Mallinckrodt's chemical processing of uranium to characterize the chemistry of the waste materials. (Duffey, p. 1, attached as **Exhibit L**.) Dr. Duffey's report explains the enrichment process removed soluble forms of thorium-230, and the remaining material in the waste would be present as a hydroxide or carbonate. (Duffey, p. 1–2.) The *Toxicological Profile for Thorium*, a publication of the ATSDR, classifies thorium hydroxide and thorium carbonate, the chemical forms of thorium-230 in the SLAPS waste, according to Duffey, as *insoluble*. (ATSDR p. 70–72). Accordingly, Dr. Wells' use of the 10 C.F.R. § 20.106 limit for soluble thorium-230 was scientifically unsupported and wrong. (Risk Assessment Corporation report, pp. 5-27, 14-15–14-20, attached as **Exhibit M**; Frazier Report, pp. 34–38, attached as **Exhibit N**.) When the correct values and characterization are used, the data shows Mallinckrodt did not release excessive thorium-230 in 1960. (Frazier Report, p. 36.)

Despite its significance, Dr. Wells did not determine the solubility of the thorium-230.[3] He admittedly did not know the chemical form of the thorium at SLAPS. (Wells Depo. 205:3–7;

[3] In reality, Dr. Wells testified he assumed the thorium was soluble as a "precautionary principle." (Wells Depo., 203:7–20.) This baseless and unscientific assumption allowed him to

207:12–16.) He also did not attempt to cure his lack of knowledge by researching the solubility of thorium-230 in guidance documents from the International Council on Radiation Protection ("ICRP") or determine whether the ICRP considers thorium soluble or insoluble. (Wells Depo., 208:9–13.) Dr. Wells also could not explain what forms were soluble versus insoluble. (Wells' Depo. 205:17–24; 205:25–206:12.) When pressed on the distinction, he gave a non-answer that "all of these things are soluble in water to – to some degree." (Wells Depo. 205:25–206:12.) Dr. Wells' non-answer, however, is scientifically wrong and would render meaningless the distinction between soluble and insoluble in Appendix B, § 20.106 and their order of magnitude limit differences.

In his report, Dr. Wells' sole reference for solubility of thorium-230 was noting the "[Department of Energy ('DOE')] used 'soluble' effluent limitations as a 'comparative guide'" in a 1979 report. (Wells Report p. 12.) The 1979 DOE report details a survey of SLAPS to "characterize the radiological status of the property." (Wells Exhibit 12, p. 3, attached as **Exhibit O**.) To provide the reader context for the measurement values, the report provides the 10 C.F.R. § 20 release limits. (Wells Report, p. 17.) Because the release limits vary by solubility of the radionuclide, the report author elected to use the "[m]ore restrictive" value from the regulation. (Wells Exhibit 12, p. 17, Table 17.) Hence, the release limit for soluble thorium-230 was used because it was a lower value, not because the DOE determined the solubility of the thorium. As further illustration, Table 17 in the DOE report lists the release rate for insoluble radium-226 because it provides the lower value. (Wells Exhibit 12, Table 17.) Given the clear statements in the DOE report, Dr. Wells' reliance on the DOE report underscores the unreliability of his methodology and analytical gap between the known facts and his opinions.

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use the lower release limit. Experts, however, should not "assume the fact to be proved." *Good v. Fluor Daniel Corp.*, 222 F. Supp. 2d 1236, 1243 (E.D. Wash. 2002).

In summary, Dr. Wells made two critical errors in rendering his opinion that Mallinckrodt released excessive thorium-230 during 1960. First, he used the highest individual measurement, not the average, inflating his input by over 60 percent. Second, without any scientific basis, Wells applied the release limit for soluble thorium-230. The effect of this baseless choice lowered the release-limit by an order of magnitude. Dr. Wells understood this and admitted that, if he used the release limit for insoluble thorium-230, there could be no violation of the standard. (Wells Depo., 213:5–18.)

3. Dr. Wells' Supplemental Opinion #3 Is Based on an Improper Methodology and Is Devoid of a Factual Basis.

In his supplemental report, Dr. Wells offers a third supplemental opinion: "Defendants' possession, use and/or transfer of wastes at SLAPS and Latty Avenue caused excessive radiation to be released in the form of contaminated sediments into Coldwater Creek and tributary ditches." (Wells Supplemental Report, p. 7.) He further claims that "releases of contaminated soil and sediment into Coldwater Creek and its tributary ditches meet the definition of the release of 'excessive radiation' as defined in 10 CFR § 20." (Wells Supplemental Report, p. 8.) To the extent this opinion is directed at Mallinckrodt, the opinion is conclusory and lacks factual support, and Dr. Wells failed to properly apply the regulation he cites or employ a reliable methodology.

As detailed throughout this brief, 10 C.F.R. § 20.106 limits releases of radioactive material, and Appendix B provides the annual average release limits for each radionuclide. Like his opinions on radon and thorium-230 releases, Dr. Wells failed to follow the methodology for determining compliance with 10 C.F.R. § 20.106 or any other provision in 10 C.F.R., Part 20. In fact, his supplemental opinion #3 does not even attempt to apply the regulation he cites. He does not specify a radionuclide he contends was released in excess of the limit; he does not state the

annual average amount released; and he does not state the applicable limit. (Wells Supplemental Report, pp. 7–8.) Dr. Wells further conceded there is insufficient data for him to quantify the releases in any given year that Mallinckrodt operated SLAPS—July 1953 to February 1966. (Wells Depo., 224:11–21.) Accordingly, Dr. Wells' opinion fails to meet the admissibility requirements of Rule 702.

Even though Dr. Wells failed to apply the 10 C.F.R., Part 20 regulations, he cited a few irrelevant measurements and reports to give the appearance of factual support. First, he quotes a 2003 Army Corps of Engineers study that provides environmental measurements of certain radionuclides. (Supplemental Report, p. 8.) These measurements are not annual average releases, and Dr. Wells could not attribute releases to any given year, rendering them meaningless for determining regulatory compliance. (Wells Depo., 224:11–21.) He also cited a 1948 document by the Atomic Energy Commission, but this document also does not provide annual average releases, and it relates to releases of radioactive materials *five years* before Mallinckrodt operated SLAPS. (Wells Supplemental Report, p. 8.) In short, this irrelevant measurement data provides no data or facts to support a conclusion about the relevant time period or Dr. Wells' *ipse dixit* conclusion that Mallinckrodt violated 10 C.F.R., Part 20, by releasing radioactive material in soil and sediment from SLAPS.

As such, Dr. Wells' supplemental opinion #3 should be excluded.

B. Dr. Wells' Allocation Opinion is Not Based on a Reliable Methodology or Sufficient Factual Data.

In order to prevail, this Court has required plaintiffs to provide "organ doses attributable to Mallinckrodt's alleged operations" at SLAPS and Cotter's alleged operations at Latty Avenue. (Doc. #741, Lead Case No. 4:12CV00361, pp. 9–10.) In his original report, Dr. Wells claims this directive requires "plaintiffs to determine what percentage of offsite contamination that plaintiffs

came into contact at various location (sic) was due to Cotter's releases and what percentage was due to Mallinckrodt's releases." (Wells Report, pp. 19–20.) Despite claiming to offer opinions as directed by the Court, Dr. Wells ignored the Court's mandate to provide expert opinions regarding releases of radioactive material attributable to Mallinckrodt's operations at SLAPS *by stating organ doses that each plaintiff received and are attributable to one defendant or the other*. Instead, he offers an "allocation" of responsibility between Cotter and Mallinckrodt that is unscientific and will mislead the jury.

A key element of the Court's Order was identifying releases "attributable to Mallinckrodt" at SLAPS. (Doc. #714, p. 10.) Dr. Wells' list of "important dates" acknowledges Mallinckrodt only operated SLAPS from 1953 to early 1966. (Wells Report, p. 12.) In his allocation discussion, Dr. Wells reiterates that Mallinckrodt started operating SLAPS in 1953. (Wells Report, p. 21, n.45.) Furthermore, he relied extensively on AEC documents from 1948 that establish radon and uranium were released from SLAPS *while the AEC and not Mallinckrodt was in control of the site*. (Wells' Report, pp. 13, 14.) Contradicting this factual background, and dodging the Court's Order, Dr. Wells falsely attributes *all* releases from SLAPS—from 1946 to 1966—to Mallinckrodt. (Wells Report, p. 21; Wells Depo., 218:12–17.) He attempts to justify this false timeline in a footnote, claiming, "it was always Mallinckrodt's waste being stored at the site." (Wells Report, p. 21, n.45.) When questioned about this comment, however, Dr. Wells claimed he only meant the wastes originated from Mallinckrodt's operation in downtown St. Louis. (Wells Depo., 95:7–24.) He did not know who owned the radioactive material at SLAPS (the AEC owned the material the entire time period of Mallinckrodt's involvement). (Wells Depo., 82:9–15; Wells Exhibit 4, attached as **Exhibit P**.) Later, he admitted plaintiffs' counsel simply instructed him to allocate all releases from SLAPS to Mallinckrodt. (Wells Depo.,

218:18–219:4; 260:22–261:9.) Thus, contrary to the Court order he professed to follow, Dr. Wells did not attempt to calculate releases attributable to *Mallinckrodt* or distinguish releases by others, even though he was aware of the factual history and knows this occurred.

Looking past his fabricated timeline inflating Mallinckrodt's involvement with SLAPS, Dr. Wells' "allocation" opinion is also not based on a reliable methodology or actual facts and data. Dr. Wells allocated release percentages between SLAPS and Latty Avenue for three time periods—pre-1966, 1966-1973, and post-1973—to four different geographical locations. (Wells Report, p. 22.) These numerical values *imply* calculation and mathematical certainty, but Dr. Wells conceded the assigned percentages were not based on calculations or modeling of actual releases of radioactive material. (Wells Depo., 220:17–221:2; 336:19–23.) He simply made them up. (Wells Depo., 336:19–23). The time periods are also nonsensical because he allocates releases from SLAPS for 1966-1973 and post-1973, when the radioactive material had already been removed from SLAPS. Given the dubious nature of his work, Dr. Wells agreed "there are a lot of data gaps," but he claimed the need for an answer trumped the lack of data. (Wells Depo., 334:1–335:10.)

Dr. Wells' proffered testimony is further deficient because it lacks any nexus to the individual plaintiffs. His report acknowledges the Court order required "organ doses." (Wells Report, p. 19.) Yet, Dr. Wells did not calculate organ doses. (Wells Depo., 217:9–14.) He ultimately conceded his allocation "isn't talking about people." (Wells Depo., 217:9–14.) Therefore, his allocation opinion is non-responsive to the question posed by the Court and would not help a jury attribute radiation exposures to the plaintiffs allegedly caused by Mallinckrodt.

In many respects, it appears Dr. Wells believed he was allocating responsibility between Cotter and Mallinckrodt to pay environmental clean-up costs, which is not the case. For instance,

his report discusses the so-called "Gore Factors." (Wells Report, p. 20–21.) The Gore factors are used by courts in apportioning clean-up costs between potentially responsible parties in an action arising under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 ("CERCLA"), 42 U.S.C. § 9601 *et seq.* *Control Data Corp. v. S.C.S.C. Corp.*, 53 F.3d 930, 935 (8th Cir. 1995). However, plaintiffs' cause of action is premised on the Price-Anderson Act, not CERCLA. (Doc. #1.) In fact, CERCLA does not even provide a "cause of action for personal injury." *CTS Corp. v. Waldburger*, 134 S. Ct. 2175, 2180 (2014). Therefore, the Gore factors have no bearing on the disputed issues in this case, and any testimony by Dr. Wells regarding the Gore factors would not help and would more likely confuse the jury.

C. Dr. Wells Is Not Qualified to Opine Regarding Compliance with the Applicable Radiation Safety Standards.

A review of Dr. Wells' lack of expertise in radiation safety shows he is unqualified to offer testimony in this case and explains the fundamental and egregious errors in his analysis. Under Federal Rule of Evidence 702, an expert witness must be qualified by "knowledge, skill, experience, training, or education." "The trial court ha[s] to decide whether this particular expert ha[s] sufficient specialized knowledge to assist the jurors in deciding the particular issues in this case." *Am. Auto. Ins. Co. v. Omega Flex, Inc.*, 783 F.3d 720, 723 (8th Cir. 2015) (alteration in original). The Eighth Circuit will affirm the exclusion or reverse the admission of testimony where an expert strays beyond their expertise. *Id.* at 724. In weighing an expert's qualifications, the court can consider "whether the expertise was developed for litigation or naturally flowed from the expert's research." *Presley v. Lakewood Eng. & Manuf. Co.*, 553 F.3d 638, 643 (8th Cir. 2009).

The gravamen of Dr. Wells' opinions against Mallinckrodt is the contention that it released radioactive material in excess of the historical federal limits imposed by 10 C.F.R. §

20.106 (1960). (Wells' Report, p. 3, 12, 14, 16, 19; Wells' Supplemental Report, p. 8.) Radiation safety and compliance with the federal regulations, however, is a "highly technical area." *McMunn*, 869 F.3d at 267. Application of these historical radiation safety regulations and the methodology for determining compliance is well beyond Dr. Wells' knowledge, skill, experience, education, or training.

Looking first to Dr. Wells' education, his college degrees are in the area of geology. (Wells Report, p. 2.) He readily admits he did not complete coursework in the relevant topics of radiation, health physics, or radiation safety. (Wells Depo., 17:11–20.) Professional memberships are another means of developing expertise, but Dr. Wells is not a member of any professional societies specific to radiation measurement or radiation safety, such as the American Board of Health Physics or Health Physics Society. (Wells Depo., 19:15–25.)

Dr. Wells' training and work experience are similarly lacking. He has never worked in a facility with a radioactive material license. (Wells Depo. 31:7–13.) He has not published a single article regarding radioactive waste, radionuclides, or radiation safety. (Wells Depo., 32:8–13.) According to the American Board of Health Physics ("ABHP"), health physics or "the science of radiation protection, is the profession devoted to protecting people and their environment from the potential radiation hazards, while making it possible to enjoy the beneficial uses of radiation."[4] The ABHP certifies qualified health physicists. (Frazier Report, p. 4.) Not only is Wells not a certified health physicist (Wells Depo, 19:15–25), he does not even meet the *minimum* professional experience requirements to apply to become a certified health physicist. (Frazier Report, p. 31.)

[4] American Board of Health Physics, https://www.aahp-abhp.org/node/19 (last visited August 11, 2021).

The same is true for Dr. Wells' experience in the relevant regulations. He concedes he is not an expert in AEC regulations. (Wells Depo., 296:20–297:1.) *In fact, this litigation is the one and only time he has ever analyzed compliance with 10 C.F.R. § 20.106 or a federal radiation safety standard.* (Wells Depo., 49:18–20; 50:2–7.) Despite being proffered as an expert witness in this PAA case, Dr. Wells admitted he did not know the standard of care applicable under the PAA. (Wells Depo., 51:5–9.) Dr. Wells' lack of expertise in these critical areas manifests itself repeatedly throughout his work: he misapplies the regulations, relies on irrelevant data, and offers result-driven opinions. Taken together, Dr. Wells' palpable lack of experience and knowledge in this highly specialized area renders him unqualified to serve as an expert witness. Any opinions he would offer will not only be unhelpful to the jury, but in many instances would be misleading.

V. CONCLUSION

For the reasons stated above, Dr. Wells' proffered testimony does not meet the requirements for admissibility under Federal Rule of Evidence 702 or the *Daubert* line of cases. Therefore, Mallinckrodt respectfully requests this Court to enter an Order excluding his opinions and testimony.

Dated: August 18, 2021

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CERTIFICATE OF SERVICE

I hereby certify that on the 18th day of August, 2021, I electronically filed the above with the Clerk of the Court by using the CM/ECF system which will send a notice of electronic filing to counsel of record.

/s/ David R. Erickson